

WHAT IS CLAIMED IS:

CLAIMS

1. A method for identifying whether a target agent is present in a  
5 biological sample comprising:

mixing capture beads, each having at least one transport probe affixed  
thereto, reporter beads, each having at least one signal probe affixed thereto,  
and a biological sample, under binding conditions so as to permit formation of  
a dual bead complex if the target agent is present in the sample, the reporter  
10 bead and capture bead each being bound to the target agent;

isolating the dual bead complex from the mixture to obtain an isolate;  
exposing the isolate to a capture field on a disc, the capture field  
having a capture agent that binds to the dual bead complex; and  
detecting the presence of the dual bead complex in the disc to indicate  
15 that the target agent is present in the sample.

2. The method of claim 1, wherein the capture beads are magnetic  
and the isolating includes subjecting the mixture to a magnetic field.

3. The method of claim 2, wherein the magnetic field is applied  
20 while the capture beads and reporter beads are on the disc.

4. The method of claim 2, wherein the capture beads and reporter  
beads are mixed off the disc and the magnetic field is applied to the mixture of  
25 the sample and the beads off the disc.

5. The method of claim 2, wherein the capture beads, reporter  
beads, and sample are mixed together and then a magnetic field is applied  
after the mixing.

6. The method of claim 2, wherein the capture beads and sample  
are mixed together, a magnetic field is applied to form a first isolate, and then  
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the first isolate is mixed with the reporter beads and a magnetic field is applied to form the isolate.

5        7.        The method of claim 1, wherein the detecting includes directing light to the capture field and detecting light reflected from the capture field.

10        8.        The method of claim 1, wherein the detecting includes directing light to the capture field and detecting light transmitted past the capture field to a detector.

15        9.        The method of claim 1, wherein the reporter beads are fluorescent, the detecting including directing light at a wavelength at which the reporter beads fluoresce, and detecting light at a wavelength emitted by the reporter beads.

20        10.       The method of claim 1, wherein the target agent includes a nucleic acid or a protein.

25        11.       The method of claim 10, wherein the target agent includes a nucleic acid, and the transport probe and the signal probe include a nucleic acid molecule complementary to the target nucleic acid.

30        12.       The method of claim 10, wherein the target agent includes a protein, and wherein the transport probe and the signal probe include an antibody that specifically binds the target protein.

35        13.       The method of claim 1, wherein the biological sample comprises blood, serum, plasma, cerebrospinal fluid, breast aspirate, synovial fluid, pleural fluid, peritoneal fluid, pericardial fluid, urine, saliva, amniotic fluid, semen, mucus, a hair, feces, a biological particulate suspension, a single-stranded or double-stranded nucleic acid molecule, a cell, an organ, a tissue, or a tissue extract.

14. The method of claim 1, wherein the reporter bead includes latex, gold, plastic, steel, or titanium.

5 15. The method of claim 1, wherein the reporter bead is fluorescent.

16. The method of claim 11, wherein the mixing is intermittent and not continuous.

10 17. The method of claim 1, wherein the transport probes comprise one or more probes selected from the group consisting of: single-stranded DNA, double-stranded DNA, single-stranded RNA, peptide nucleic acid, biotin, streptavidin, an antigen, an antibody, a receptor protein and a ligand.

15 18. The method of claim 1, wherein the dual bead complex specifically binds to the capture agent via the signal probe or the reporter bead or any combination thereof.

20 19. The method of claim 1, wherein one of the reporter bead and signal probe is biotinylated and the capture agent is streptavidin or neutravidin.

25 20. The method of claim 1, wherein the exposing includes rotating the disc to move the dual bead complex to the capture field, the method further including rotating the disc in order to cause unbound dual bead complex to be moved away from the capture field.

30 21. The method of claim 1, wherein the capture agent is affixed to the capture layer via an amino group or a thiol group.

22. The method of claim 1, wherein the target agent includes one of a nucleic acid characteristic of a disease, a nucleic acid having a nucleotide

sequence specific for a person, a nucleic acid having a nucleotide sequence specific for an organism, a nucleic acid molecule associated with cancer in a human, an antibody which is present only in a subject infected with HIV-1, a viral protein antigen, or a protein characteristic of a disease state in a subject.

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23. The method of claim 1, wherein the target agent includes a nucleic acid having a nucleotide sequence specific for an organism, and the organism is a bacterium, a virus, a mycoplasm, a fungus, a plant, or an animal.

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24. The method of claim 1, wherein the capture beads include a first group of capture beads and a second group of capture beads, the first and second groups being different.

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25. The method of claim 1, wherein the reporter beads include a first group of reporter beads and a second group of reporter beads, the first and second groups being different.

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26. The method of claim 1, wherein the dual bead complex is in a chamber within the disc, the chamber including a first capture field and a second capture field fluidly coupled to the first capture field.

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27. The method of claim 26, further comprising providing a first capture agent in the first capture field, and a second capture agent, different from the first capture agent, in the second capture field, the chamber thereby being adapted to detect either or both of two different target agents.

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28. The method of claim 26, further comprising providing a first capture agent and a second capture agent, different from the first capture agent, in the same capture field, the capture field thereby being adapted to detect either or both of two different target agents.

29. A disc for detecting a target agent comprising:  
a substrate;  
a capture layer associated with the substrate;  
capture agent at the capture layer; and
- 5 a dual bead complex including a reporter bead with a transport probe bound to the target agent, a capture bead with a signal probe bound to the target agent, one of the transport probe and signal probe being bound to the capture agent.
- 10 30. The disc of claim 29, wherein the target agent comprises a nucleic acid or a protein.
31. The disc of claim 29, wherein the reporter bead is fluorescent.
- 15 32. The disc of claim 31, wherein the fluorescent reporter bead is yellow, green, red or blue.
33. The disc of claim 29, wherein the capture bead is magnetic.
- 20 34. The disc of claim 29, wherein one of the reporter bead, capture bead, transport probe, or signal probe is biotinylated and the capture agent is streptavidin or neutravidin.
- 25 35. The disc of claim 29, wherein the capture layer includes a first capture field and a second capture field spaced from the first capture field but fluidly coupled thereto, each capture field having affixed thereto a different capture agent.
- 30 36. The disc of claim 29, wherein the disc has a mixing chamber pre-loaded with capture beads and reporter beads for receiving a sample, a waste chamber for unbound reporter beads, and a detection chamber for receiving dual bead complexes and including the capture field.

37. The disc of claim 36, further comprising means for directing a portion of the sample to the waste chamber, and then a portion of the sample to the detection chamber.

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38. The disc of claim 37, wherein the directing means includes a movable member that blocks one passage when rotated in one direction and blocks another passage when the disc is rotated in a direction opposite the one direction.

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39. The disc of claim 37, wherein the directing means includes a material in a passage to one of the waste chamber or detection chamber and that controllably solidified or dissolves.

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40. The disc of claim 37, wherein the directing means includes a configuration of chambers and passages.

41. A disc system for detecting a target agent comprising:  
a biodisc having a first capture field and adapted to allow a first dual bead complex including a reporter bead with a transport probe bound to the target agent, and a capture bead with a signal probe bound to the target agent, to be bound to the capture field; and  
a detection system including:  
an energy source for directing energy to the capture field, and  
a detector for detecting energy to determine the presence of the dual bead complex in the capture field.

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42. The system of claim 41, wherein the energy source emits light at a desired wavelength.

43. The system of claim 41, wherein the reporter bead is fluorescent, the wavelength of the light source being a wavelength at which the reporter bead fluoresces.

5           44. The system of claim 41, wherein the disc has encoded data therein, the wavelength of the light source is controllable in response to data read from the disc.

10           45. The system of claim 41, the energy source and detector being on the same side of the disc, the detector detecting light reflected from the dual bead complex in the capture field.

15           46. The system of claim 41, the energy source and detector being on opposite sides of the disc, the detector detecting light transmitted through the disc around the dual bead complex in the capture field.

            47. The system of claim 41, wherein the system can detect a sample at a concentration of  $10E-16$  M.

20           48. The system of claim 41, wherein the capture beads are magnetic, the detection system including a magnet that can be positioned near the optical disc.

25           49. The system of claim 41, wherein the drive is a magneto-optic drive that can form selected magnetic regions on the disc.

30           50. The system of claim 41, wherein the disc has a mixing chamber for receiving the sample, the detection system further comprising an electromagnet positioned to controllably apply a magnetic field to the mixing chamber.

51. A disc comprising:  
a substrate;  
a capture layer associated with the substrate and including a capture agent in a capture field; and  
5 a mixing chamber within the disc and spaced from the capture field, the mixing chamber pre-loaded before receiving a sample with reporter beads with transport probes bound thereto and capture beads with signal probes bound thereto, the transport probes and signal probes each capable to binding with a target agent, the disc being adapted to receive a sample in the  
10 mixing chamber, to mix the sample with the reporter beads and capture beads to produce dual bead complex structures, and to provide the dual bead complex structures to the capture field.

52. The disc of claim 51, further comprising a waste chamber fluidly  
15 coupled to the mixing chamber for receiving reporter beads not bound to capture beads.

53. The disc of claim 52, further comprising rotationally dependent valve means for controllably directing the sample to the waste chamber or the  
20 detection chamber.

54. The disc of claim 53, wherein the valving means directs flow based on the direction of rotation of the disc.

25 55. A biodisc system for detecting a target agent comprising:  
a biodisc having a first capture field and adapted to allow a first dual bead complex including a reporter bead with a transport probe bound to the target agent, and a capture bead with a signal probe bound to the target agent, to be bound to the capture field, wherein the capture field includes  
30 regions on the disc that can be made magnetic; and  
a drive system including a write head for forming magnetic regions on the disc for capturing dual bead complexes.



56. The system of claim 55, the drive further including:  
an energy source for directing energy to the magnetic regions,  
and  
5 a detector for detecting the energy to determine the presence of  
the dual bead complex in the capture field.

57. The system of claim 55, wherein the disc is a magneto-optical  
disc, and the drive has a magneto-optical write head capable of erasing  
10 magnetic regions.

58. A method including using a disc drive write head to form magnetic  
regions in a biodisc, introducing a magnetic beads bound to a biological  
sample so that it magnetically binds to the magnetic region, and detecting the  
15 sample bound to the bead.

59. The method of claim 58, wherein the disc drive is a magneto-  
optical drive.

20 60. The method of claim 58, further comprising erasing the magnetic  
region, thereby allowing the magnetic bead to be released.